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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,632	11/17/2003	Michael E. Mendelsohn	00398/518002	4319

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EXAMINER	
GEBREYESUS, KAGNEW H	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,632	MENDELSOHN ET AL.	
	Examiner	Art Unit	
	Kagnew H Gebreyesus	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-4 are drawn to a protein sequence (95% identical to the myosin phosphatase-Rho interacting protein (M-RIP)) of SEQ ID NO 1, classified in class 530, subclass 350.

Group II. Claims 5-9 drawn to nucleic acid sequence, (SEQ ID NO 19) classified in class 536, subclass 23.5.

Group III. Claims 10-15 are drawn to a method of screening for a compound used for treating, reducing or preventing hypertension or hypertensive conditions as measured by reduced expression of M-RIP in a mammalian cell classified in class 435 subclass 6.

Group IV. Claims 16-20 are drawn to a method of screening for a compound used for treating, reducing or preventing hypertension or hypertensive conditions as determined by binding of the candidate compound to human M-RIP protein thereby reducing its activity as measured by reduced binding of M-RIP to myosin phosphatase and/or RhoA in cell free *in-vito* system classified in class 435, subclass 21.

Group V. Claims 21-24, 27, 28, (29-33) in part are drawn to a method of treating, reducing or preventing hypertension or hypertensive conditions characterized as a cardiovascular condition in a human comprising,

administration of a therapeutically effective dose of an agent that reduces the level or activity of M-RIP by at least 10% classified in class 514, subclass 789.

Group VI. Claims 21-23, 25, 27, 28, (29-33) in part are drawn to a method of treating, reducing or preventing hypertension or hypertensive conditions characterized as a cerebrovascular condition in a human comprising, administration of a therapeutically effective dose of an agent that reduces the level or activity of M-RIP by at least 10% classified in class 514, subclass 789.

Group VII. Claims 21-23, 26, 27, 28, (29-33) in part are drawn to a method of treating, reducing or preventing hypertension or hypertensive conditions characterized as a renal condition in a human comprising, administration of a therapeutically effective dose of an agent that reduces the level or activity of M-RIP by at least 10% classified in class 424, subclass 14.

Group VIII. Claims 34 and 35 are drawn to a kit containing an therapeutic agent and a instructions for delivering the agent to reduce the level or activity of M-RIP by reducing M-RIP binding to myosine phosphatase, RhoA or both classified in class 514, subclass 789.

2. Inventions in Group I are related to Group II as protein and DNA that encodes the protein. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions since they are physically and

functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as synthetic peptide synthesis or purification from a natural source. Further the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

3. Inventions Group I and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group III, the process of measuring the levels of M-RIP can be achieved by measuring the mRNA levels. In addition the protein of Group I can be used to induce antibodies.

4. Inventions in Group I and in Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group I can be used to induce antibodies.

5. Inventions in Group II and in Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Group III, the process of measuring the levels of M-RIP can be achieved by measuring the protein levels. In addition the nucleic acid of Group II can be used to make the protein.

6. Inventions Group II and Group IV are independent. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product in Group II cannot be made by or used directly in the method of Group IV.

7. Both Group I and in Group II inventions are unrelated to the methods of treatment of Groups V-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein product of Group I and the nucleic acid of Group II cannot be made or be used in the processes of Group V-VII. The processes of Group V-VII use an agent that inhibits M-RIP.

8. Inventions in Group I and Group II are patentably distinct from invention in Group VIII because Group VIII is drawn to a therapeutic agent and mode of delivery of the same for treating reducing, or preventing hypertension and Group I is drawn to the M-RIP protein and Group II is

drawn to DNA encoding M-RIP protein thus the protein of Group I and the DNA of Group II are physically and functionally different from the therapeutic agent of Group VIII.

9. Although there are no provisions under the section for "Relationship of Inventions" in the MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of screening of Group III and method of treatment of Group V, VI and VII because of the following reasons: The screening method of Group III measures expression level of the mRNA/protein, or the activity of the M-RIP in a mammalian cell in view of identifying a therapeutic agent, while the method of Group V, VI and VIII involve treatment with an agent. Thus the two methods recite structurally and functionally distinct elements are not required one for the other and achieve different goals.

10. The methods of screening of Group IV and method of treatment of Group V, VI and VII are distinct because of the following reasons: The method of Group IV is drawn to screening for a therapeutic agent by measuring binding of M-RIP to myosine phosphatase and/or RhoA in a cell free in vitro in view, while the method of Group V, VI and VII involve treatment with an agent that presumably possesses a therapeutic effect. Thus the two methods recite structurally and functionally distinct elements are not required one for the other and achieve different goals.

11. The methods of Group III and IV are distinct from the product of Group VIII. The kit of Group VIII and the screening methods of Groups III and IV are a product and a method. The screening method of Group III and IV measures expression level of the mRNA/protein, or the

activity of the M-RIP in a mammalian cell in view of identifying a therapeutic agent, while the product of Group VIII involve the use of the therapeutic agent and the modality of treatment. The methods of Group III and IV neither make or use the kit of Group VIII.

12. The methods of treatment of Group V, VI and VII are distinct from each other because each requires different steps and achieves different results. Therefore a search and examination of each method in Group V, VI and Group VII in one patent application would result in undue burden, since the searches for the three groups are not co-extensive, the classification is different, and the subject matter is divergent.

13. Inventions In Group VIII and Groups V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a kit could be used in immunoaffinity purifying myosine phosphatase or M-RIP.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include

all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagnew Gebreyesus
Art Unit 1652
571-272-2937

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PRIMARY EXAMINER
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